

Deposit of Microorganisms for Purposes of Patent Procedure. For the cytotoxin protein (CT):

ATCC No.: 69157 *E. coli* TG1 containing the plasmid TOXHH1

ATCC No.: n/a *E. coli* TG1 containing the plasmid TOXEE1

For the CAI protein:

ATCC No. 69158 *E. coli* TG1 containing the plasmid 57/D

ATCC No. 69159 *E. coli* TG1 containing the plasmid 64/4

ATCC No. 69160 *E. coli* TG1 containing the plasmid P1-24

ATCC No. 69161 *E. coli* TG1 containing the plasmid B/1

For the heat shock protein (hsp):

ATCC No. 69155 *E. coli* TG1 containing the plasmid pHp60G2

ATCC No. 69156 *E. coli* TG1 containing the plasmid pHp605.--

IN THE CLAIMS:

Please cancel claims 38, 39, 42, 44, 48, 50, 51, 53, 60, 61, 64-66, 71, 73, 74, 77, and 79 without disclaimer or prejudice to reintroduction at a later time.

Please amend claims 40, 45, 47, 54, 56, 57, 59, 62, 63, 70, 7576, 78, and 80 to read as follows:

40. (Twice amended) A purified polypeptide comprising the amino acid sequence of SEQ ID NO:5.

45. (Three times amended) A purified polypeptide comprising at least ten contiguous amino acids of SEQ ID NO:5, which polypeptide: (i) can be used to induce the production of antibodies to *Helicobacter pylori* CAI antigen, and (ii) is substantially noncytotoxic.

47. (Three times amended) The polypeptide of claim 45 which comprises at least fifteen contiguous amino acids of SEQ ID NO:5.

54. (Three times amended) A prophylactic or therapeutic vaccine comprising an immunologically effective amount of a recombinant polypeptide, which recombinant polypeptide: (i) comprises at least ten contiguous amino acids of SEQ ID NO:5, (ii)

E8 can be used to induce the production of antibodies to *Helicobacter pylori* CAI antigen, and (iii) is substantially noncytotoxic.

56. (Three times amended) The vaccine of claim 54 wherein said polypeptide comprises at least fifteen contiguous amino acids of SEQ ID NO:5.

E9
Sub F3
57. (Three times amended) The vaccine of claim 54 further comprising an immunologically effective amount of a second polypeptide, which second polypeptide: (i) comprises at least ten contiguous amino acids of *Helicobacter pylori* heat shock protein, (ii) can be used to induce the production of antibodies to *Helicobacter pylori* heat shock protein, and (iii) is substantially noncytotoxic.

Sub F4
F10
59. (Three times amended) The vaccine of claim 57 wherein said second polypeptide comprises at least fifteen contiguous amino acids of *Helicobacter pylori* heat shock protein.

Sub F5
E11
62. (Three times amended) A method of preparing a prophylactic or therapeutic vaccine comprising bringing into association:

- (1) an immunologically effective amount of a purified polypeptide, which polypeptide: (i) comprises at least ten contiguous amino acids of SEQ ID NO:5, (ii) can be used to induce the production of antibodies to *Helicobacter pylori* CAI antigen, and (iii) is substantially noncytotoxic, and
- (2) a pharmaceutically acceptable carrier.

63. (Three times amended) The method of claim 62 or 78 further comprising adding an immunologically effective amount of a second polypeptide, which second polypeptide: (i) comprises at least ten contiguous amino acids of *Helicobacter pylori* heat shock protein, (ii) can be used to induce the production of antibodies to *Helicobacter pylori* heat shock protein, and (iii) is substantially noncytotoxic.

Sub F6
E12
70. (Twice amended) The vaccine of claim 54, further comprising an immunologically effective amount of a second polypeptide, wherein said second polypeptide: (i) comprises at least ten contiguous amino acids of *Helicobacter pylori*

E12

cytotoxin (CT) protein, (ii) can be used to induce the production of antibodies to *Helicobacter pylori*, and (iii) is substantially noncytotoxic.

Sub
E11
E13

75. (Amended) A recombinant polypeptide comprising at least ten contiguous amino acids of SEQ ID NO:5, which recombinant polypeptide: (i) can be used to induce the production of antibodies to *Helicobacter pylori* CAI antigen, and (ii) is substantially noncytotoxic.

76. (Amended) The polypeptide of claim 75 which comprises at least fifteen contiguous amino acids of SEQ ID NO:5.

Sub
E14
E15

78. (Amended) A method of preparing a prophylactic or therapeutic vaccine comprising bringing into association:

- (1) an immunologically effective amount of a recombinant polypeptide, which recombinant polypeptide: (i) comprises at least ten contiguous amino acids of SEQ ID NO:5, (ii) can be used to induce the production of antibodies to *Helicobacter pylori* CAI antigen, and (iii) is substantially noncytotoxic, and
- (2) a pharmaceutically acceptable carrier.

E15 Sub
E16

80. (Amended) The vaccine of claim 70 wherein said second polypeptide comprises at least fifteen contiguous amino acids of *Helicobacter pylori* CT protein.

Please add the following new claims 81-139:

Sub
E10

81. (New) An isolated immunogenic polypeptide comprising at least five contiguous amino acids from SEQ ID NO:5.

82. (New) The polypeptide of claim 81, said polypeptide comprising at least ten contiguous amino acids from SEQ ID NO:5.

83. (New) The polypeptide of claim 81, said polypeptide comprising at least fifteen contiguous amino acids from SEQ ID NO:5.

84. (New) The polypeptide of claim 81, 82, or 83, said polypeptide further comprising *Helicobacter pylori* cytotoxin associated immunodominant (CAI) antigen, an

immunogenic fragment of *Helicobacter pylori* CAI antigen, or an immunogenic derivative of *Helicobacter pylori* CAI antigen.

85. (New) The polypeptide of claim 84, said polypeptide comprising an immunogenic fragment of *Helicobacter pylori* CAI antigen.

86. (New) The polypeptide of claim 84, said polypeptide comprising an immunogenic derivative of *Helicobacter pylori* CAI antigen.

87. (New) The polypeptide of claim 81, said polypeptide comprising amino acids 1-1147 of SEQ ID NO:5.

88. (New) The polypeptide of claim 84, wherein said polypeptide is a recombinant polypeptide.

89. (New) The polypeptide of claim 81, said polypeptide comprising *Helicobacter pylori* CAI antigen, an immunogenic fragment of *Helicobacter pylori* CAI antigen, or an immunogenic derivative of *Helicobacter pylori* CAI antigen which is immunogenically identifiable with the protein encoded by SEQ ID NO:5.

90. (New) The polypeptide of claim 81, said polypeptide further comprising one or more amino acid substitutions or deletions, wherein said amino acid substitutions or deletions do not substantially affect the functional aspects of said antigen.

91. (New) The polypeptide of claim 90, wherein said amino acid substitution is a conservative amino acid replacement.

92. (New) An isolated immunogenic polypeptide comprising at least five contiguous amino acids from SEQ ID NO:5 and further comprising SEQ ID NO:12.

93. (New) The polypeptide of claim 81, said polypeptide comprising at least five contiguous amino acids from amino acids 707-937 of SEQ ID NO:5.

94. (New) The polypeptide of claim 92, comprising at least ten contiguous amino acids of SEQ ID NO:5.

95. (New) The polypeptide of claim 92, comprising at least fifteen contiguous amino acids of SEQ ID NO:5.

96. (New) The polypeptide of claim 92, 94, or 95, further comprising *Helicobacter pylori* CAI antigen, an immunogenic fragment of *Helicobacter pylori* CAI antigen, or an immunogenic derivative of *Helicobacter pylori* CAI antigen.

97. (New) The polypeptide of claim 96, comprising an immunogenic derivative of *Helicobacter pylori* CAI antigen.

98. (New) The polypeptide of claim 96, said polypeptide comprising an immunogenic fragment of *Helicobacter pylori* CAI antigen.

1-16
cont

99. (New) An isolated immunogenic polypeptide comprising at least five contiguous amino acids from SEQ ID NO:5 and further comprising one or more of the amino acid sequences selected from the group consisting of SEQ ID NO:10, SEQ ID NO:14, SEQ ID NO:16, and SEQ ID NO:17.

100. (New) An isolated immunogenic polypeptide comprising at least five contiguous amino acids from SEQ ID NO:5 and further comprising the amino acid sequence of SEQ ID NO:17.

101. (New) The polypeptide of claim 99 or 100, said polypeptide further comprising a *Helicobacter pylori* CAI antigen, an immunogenic fragment of *Helicobacter pylori* CAI antigen, or an immunogenic derivative of *Helicobacter pylori* CAI antigen.

102. (New) The polypeptide of claim 101, said polypeptide comprising an immunogenic fragment of a *Helicobacter pylori* CAI antigen.

103. (New) The polypeptide of claim 101, said polypeptide comprising an immunogenic derivative of a *Helicobacter pylori* CAI antigen.

104. (New) The polypeptide of claim 99 or 100, wherein the polypeptide comprises at least ten contiguous amino acids from SEQ ID NO:5.

105. (New) The polypeptide of claim 99 or 100, wherein the polypeptide comprises at least fifteen contiguous amino acids from SEQ ID NO:5.

106. (New) The polypeptide of claim 99, said polypeptide comprising the amino acid sequence of SEQ ID NO:14.

107. (New) The polypeptide of claim 99, said polypeptide comprising the amino acid sequence of SEQ ID NO:16.

108. (New) The polypeptide of claim 99, said polypeptide comprising the amino acid sequence of SEQ ID NO:17.

109. (New) The polypeptide of claim 81, said polypeptide comprising at least amino acid positions 748 to 977 of SEQ ID NO:5.

110. (New) An isolated immunogenic polypeptide comprising at least five contiguous amino acids from SEQ ID NO:5 and further wherein said polypeptide comprises one or more of the amino acid sequences selected from the group consisting of SEQ ID NO:9, SEQ ID NO:10, SEQ ID NO:17, and SEQ ID NO:23.

111. (New) The polypeptide of claim 110, wherein said polypeptide comprises at least ten contiguous amino acids from SEQ ID NO:5.

112. (New) The polypeptide of claim 110, wherein said polypeptide comprises at least fifteen contiguous amino acids from SEQ ID NO:5.

113. (New) The polypeptide of claim 110, 111, or 112, said polypeptide further comprising a *Helicobacter pylori* CAI antigen, an immunogenic fragment of *Helicobacter pylori* CAI antigen, or an immunogenic derivative of *Helicobacter pylori* CAI antigen.

114. (New) The polypeptide of claim 113, said polypeptide comprising an immunogenic derivative of a *Helicobacter pylori* CAI antigen.

115. (New) The polypeptide of claim 113, said polypeptide comprising an immunogenic fragment of a *Helicobacter pylori* CAI antigen.

116. (New) The polypeptide of claim 110, said polypeptide comprising the amino acid sequence of SEQ ID NO:9.

117. (New) The polypeptide of claim 110, said polypeptide comprising the amino acid sequence of SEQ ID NO:10.

118. (New) The polypeptide of claim 110, said polypeptide comprising the amino acid sequence of SEQ ID NO:17.

119. (New) The polypeptide of claim 110, said polypeptide comprising the amino acid sequence of SEQ ID NO:23.

120. (New) The polypeptide of claim 110, said polypeptide comprising at least five contiguous amino acids from amino acid position 600 to amino acid position 900 of SEQ ID NO:5.

121. (New) An isolated immunogenic polypeptide comprising at least five contiguous amino acids of SEQ ID NO:12.

122. (New) An isolated immunogenic polypeptide comprising at least five contiguous amino acids of SEQ ID NO:17.

123. (New) An isolated immunogenic polypeptide encoded by at least fifteen contiguous nucleotides of SEQ ID NO:4.

124. (New) An isolated immunogenic polypeptide encoded by at least thirty contiguous nucleotides of SEQ ID NO:4.

125. (New) An isolated immunogenic polypeptide encoded by at least forty-five contiguous nucleotides of SEQ ID NO:4.

126. (New) The polypeptide of claim 123, 124, or 125, said polypeptide comprising *Helicobacter pylori* CAI antigen, an immunogenic fragment of *Helicobacter pylori* CAI antigen, or an immunogenic derivative of *Helicobacter pylori* CAI antigen.

127. (New) The polypeptide of claim 123, said polypeptide encoded by the polynucleotide sequence of SEQ ID NO:4.

128. (New) The polypeptide of claim 126, wherein said polypeptide is a recombinant polypeptide.

129. (New) The polypeptide of claim 123, further encoded by the polynucleotide sequence of SEQ ID NO:11.

130. (New) The polypeptide of claim 123, said polypeptide encoded by at least fifteen contiguous nucleotides of nucleotide positions 2772-3466 of SEQ ID NO:4.

131. (New) The polypeptide of claim 124, further encoded by the polynucleotide sequence of SEQ ID NO:11.

132. (New) The polypeptide of claim 125, further encoded by the polynucleotide sequence of SEQ ID NO:11.

133. (New) The polypeptide of claim 129, 131, or 132, comprising *Helicobacter pylori* CAI antigen, an immunogenic fragment of *Helicobacter pylori* CAI antigen, or an immunogenic derivative of *Helicobacter pylori* CAI antigen.

134. (New) The polypeptide of claim 123, further encoded by at least one or more of the polynucleotide sequences selected from the group consisting of SEQ ID NO:13, SEQ ID NO:15, and SEQ ID NO:18.

135. (New) The polypeptide of claim 134, comprising *Helicobacter pylori* CAI antigen, an immunogenic fragment of *Helicobacter pylori* CAI antigen, or an immunogenic derivative of *Helicobacter pylori* CAI antigen.

136. (New) The polypeptide of claim 124, further encoded by at least one or more of the polynucleotides sequences selected from the group consisting of SEQ ID NO:13, SEQ ID NO:15, and SEQ ID NO:18.

137. (New) The polypeptide of claim 125, further encoded by at least one or more of the polynucleotides sequences selected from the group consisting of SEQ ID NO:13, SEQ ID NO:15, and SEQ ID NO:18.

138. (New) The polypeptide of claim 99, said polypeptide comprising the amino acid sequence of SEQ ID NO:10.

139. (New) An isolated immunogenic polypeptide comprising the amino acid sequence of SEQ ID NO:10.

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